REMARKS

I. Support for Amendments

Claims 1, 8-11 and 13 have been amended. Upon entry of the foregoing amendments, claims 1 and 8-13 are pending in the application. Support for these amendments may be found throughout the specification and in the original claims, for example at page 9, line 24 through page 10, line 7; at page 16, lines 20-25; at page 19, line 1 through page 20, line 12; and at page 25, line 21 through page 27, line 20. No new matter enters by these amendments.

Applicants thank the Examiner for withdrawing the rejection of claim 1 under 35 U.S.C. § 112, second paragraph. Applicants also thank the Examiner for returning the Examiner-initialed Form 1449.

II. Rejection under 35 U.S.C. § 102(e)

Claim 1 stands rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Klann, U.S. Patent No. 6,068,974, filed on April 29, 1998. Office Action at page 2. The Office alleges that "Klann discloses a 674 base pair purified nucleic acid molecule containing a 7 base pair fragment at 425 of SEQ ID NO:1 (See column 13, lines 1-20)." Office Action at page 2. The Office asserts that the claim language recites "a substantially purified nucleic acid molecule...comprising a nucleic acid sequence of SEQ ID NO:1" (emphasis in original), and that "[t]he limitation reads on the teachings of Klann." Office Action at page 2. Applicants respectfully disagree.

It is axiomatic that for prior art to anticipate under § 102, it has to meet every element of the claimed invention. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986). An anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device. *In re Donohue*, 766 F.2d 531, 226 U.S.P.Q 619 (Fed. Cir. 1985).

With regard to the phrase "or fragment thereof," Applicants respectfully point out that a grammatically consistent interpretation of the claim at issue would relate the phrase "or fragment thereof" in the preamble back to the phrase "maize protein" directly preceding it. Further, because the phrase "or fragment thereof" appears before the transition phrase "comprising", it is clear that it does not refer to a fragment of SEQ ID NO: 1. Moreover, Applicants assert that the Examiner has placed undue emphasis on the phrase "a nucleic acid sequence of" while simultaneously disregarding the recitation of SEQ ID NO: 1 in the claim. Applicants respectfully submit that the Examiner has erred in doing so. "Claims are not to be read in a vacuum, and limitations therein are to be interpreted in light of the specification in giving them their 'broadest reasonable interpretation.'" *In re Marosi*, 710 F.2d 799, 802, 218 U.S.P.Q. 289, 292 (Fed. Cir. 1983), quoting *In re Okuzawa*, 537 F.2d 545, 548, 190 U.S.P.Q. 464, 466 (C.C.P.A. 1976)(emphasis in original). See also M.P.E.P. § 2111.01 at 2100-48.

As such, the Examiner's interpretation of claim 1 to cover fragments of the claimed nucleic acid molecules as short as seven nucleotides is unreasonable and inconsistent with the teachings of the specification. Applicants therefore disagree that claim 1 reads on the teachings of Klann. However, in order to facilitate prosecution, and without acquiescing to the Examiner's interpretation of claim 1, Applicants have amended claim 1.

Pending claim 1 is directed to a nucleic acid molecule which encodes a maize protein or fragment thereof, *i.e.*, a fragment of a maize protein, comprising the nucleic acid sequence of SEQ ID NO: 1. Whatever U.S. Patent No. 6,068,974 teaches, it does not disclose SEQ ID NO: 1. Absent a teaching of each and every element of the claim, including the nucleotide sequence of SEQ ID NO: 1, the reference cited by the Examiner does not anticipate pending claim 1.

In view of the above, Applicants contend the rejection under 35 U.S.C. § 102(e) is improper. Reconsideration and withdrawal of this rejection is respectfully requested.

III. Rejection under 35 U.S.C. § 101 (Utility)

Claims 1 and 8-13 stand rejected under 35 U.S.C. § 101, first paragraph, as allegedly lacking a "specific and substantial" asserted utility or a well-established utility. The Office alleges that "[a]s set forth in the Office Action mailed 4/09/2003 the disclosed use of the nucleic acid is generally applicable to any nucleic acid and is therefore not particular to the nucleic acid sequence being claimed." Office Action at page 3. The Office further asserts that there is not any art of record that discloses or suggests any property or activity for the nucleic acid molecules. Office Action at page 3. Applicants respectfully disagree.

Applicants respectfully submit that the application of the Interim Guidelines ignores the presently disclosed utilities and contravenes well-established doctrines of utility developed in the courts. It is well-established law that "when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983).

Applicants respectfully submit that the specification describes multiple objectives and utilities that are met by the present invention. For example, the claimed nucleic acid molecules are useful in determining the presence of polymorphisms, isolating specific promoter sequences, and obtaining nucleic acid homologues. (*see, e.g.,* specification, beginning at page 34, under heading "Uses of the Agents of the Invention").

The Office alleges that there is not any art of record that discloses or suggests any property or activity for the nucleic acid molecules. Office Action at page 3. Applicants respectfully disagree. The nucleic acid molecules of the present invention are derived from young maize seedlings, and as such, they may function in plant growth, quality, yield, and could also serve as links in important metabolic, developmental, and catabolic pathways. *See, e.g.,* specification at page 34, lines 4-20. Moreover, the nucleic acid molecules of the present invention are generated from cold-treated young maize seedlings and from cold tolerant germplasm WIGOR, and may enable acquisition of cold-response

genes, cold-resistance genes, and genes that encode cold regulatory transactivation proteins. *See, e.g.,* specification at page 34, line 21 through page 35, line 8.

Applicants further note that it is standard practice to use nucleic acids of known sequence (*e.g.,* SEQ ID NO: 1) to perform gene expression analysis using methods such as microarray technology. Knowing that an RNA corresponding to the claimed nucleic acid molecule is expressed under certain conditions or in certain tissues or at certain levels is in itself useful. For example, such information is useful to detect and compare expression changes in tissue samples taken from organisms grown under different conditions, *e.g.*, drought stress, cold stress, exposure to pathogens, or exposure to chemical compounds. SEQ ID NO: 1 might be differentially expressed, for example, under one or more growth conditions that tend to induce expression changes in genes involved in plant growth (*e.g.,* growth in the presence of plant hormones), or conditions that tend to induce expression changes in cold-response genes or cold-resistance genes. *See, e.g.,* specification at page 34, line 4 through page 35, line 8. Microarrays allow rapid, simultaneous expression analysis of thousands of sequences, and thus, informative *patterns* of expression are derived from the microarray expression data. For at least these reasons, Applicants respectfully submit that expression analysis is a **use** of SEQ ID NO: 1 in a real world context. Applicants further submit that the specification teaches one of skill in the art how to use SEQ ID NO: 1 for this purpose. *See, e.g.,* specification at page 55, line 8 through page 58, line 23 (describing use of SEQ ID NO: 1 for microarray analysis of gene expression profiles).

The Examiner asserts that "each utility should be addressed in the specification." Office Action at page 3. Applicants respectfully submit that the specification does address the aforementioned utilities. *See, e.g.,* specification at page 55, line 8 through page 58, line 23 (describing use of SEQ ID NO: 1 for microarray analysis of gene expression profiles); and specification, beginning at page 34, under heading "Uses of the Agents of the Invention" (describing use of SEQ ID NO: 1 for identifying polymorphisms, isolating specific promoter sequences, and obtaining nucleic acid homologues).

Many of the uses described in the specification are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell, or organism. Significantly, the utility of a microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.,* the claimed nucleic acid molecules may be used to identify and characterize nucleic acid molecules within a sample, cell, or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed sequences possess the requisite utility under 35 U.S.C. § 101.

In the Office Action, the Examiner attempts to undermine the existing utilities by stating that they are "generally applicable to any nucleic acid and is therefore not particular to the nucleic acid sequence being claimed," Office Action at page 3. In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renshaw PLC,* 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result...").

Such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.,* hitting golf balls. Such a result is not only untenable, but requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty,* 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

Applicants note that the claimed nucleic acid molecules encompass many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and isolate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a ***unique*** subset of related sequences. This subset of related sequences is specific to the claimed sequence and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit the ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid molecules exhibit the requisite utility under 35 U.S.C. § 101.

The Examiner states that the credibility of the presently asserted utilities has not been assessed. Office Action at page 3. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Examiner "must do more than merely question operability – [she] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert,* 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 2107.01 ("Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided..."). Here, the Examiner has not even attempted to meet this burden. Thus, the Examiner's admission that the credibility of the disclosed utilities is not challenged is tantamount to an admission that no proper rejection has been made.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. An invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the rejection under 35 U.S.C. § 101 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

IV. Rejection under 35 U.S.C. § 112, First Paragraph (Enablement)

Claims 1 and 8-13 stand rejected under 35 U.S.C. § 112, first paragraph, on the grounds that, as claims 1 and 8-13 allegedly lack a "specific and substantial" asserted utility or a well-established utility, one skilled in the art would therefore allegedly not know how to use the claimed invention so that it would operate as intended without undue experimentation. Office Action at page 4. Applicants respectfully traverse this rejection, and submit that this rejection has been overcome by the foregoing arguments regarding utility. Applicants therefore respectfully request reconsideration and withdrawal of the enablement rejections under 35 U.S.C. § 112, first paragraph.

V. Rejection under 35 U.S.C. § 112, First Paragraph (Enablement)

Claims 1 and 8-13 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which is allegedly not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention without undue experimentation. Office Action at page 3. The Office alleges that "[t]he variants of the fragment of SEQ ID NO: 1 is extremely complex and unpredictable and the specification does not provide an adequate guidance as to the nature of active derivatives that may be constructed." Office Action at page 4. The Office further asserts that "the claim only claims [that] a substantially purified nucleic acid molecule that encodes a maize protein

or fragment comprising a nucleic acid sequence of SEQ ID NO:1," which the Office alleges "is not a complete chemical structure of SEQ ID NO:1." Office Action at page 4. Applicants respectfully disagree.

Applicants disagree with the Office's implied assertion that the complete chemical structure of SEQ ID NO: 1 has not been described. Applicants respectfully submit that the complete chemical structure of SEQ ID NO: 1 has indeed been described in the sequence listing.

Applicants also submit that the specification disclosure is adequate to enable one of skill in the art to identify, without undue experimentation, the variants of SEQ ID NO: 1 that are encompassed by the claims. For example, the specification describes the degeneracy of the genetic code (*see, e.g.,* specification at page 22, lines 16-23), conservative amino acid substitutions (*see, e.g., s*pecification at page 22, line 24 through page 25, line 20), and the identification of single nucleotide polymorphisms (*see, e.g.,* specification at page 26, line 10 through page 27, line 20). It is well-established that patent applicants need not teach "conventional and well-known genetic engineering techniques," such as routine functional screening or nucleic acid sequencing of putative mutant clones. *See, e.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000). Performing routine and well-known steps cannot create undue experimentation even if it is laborious. *See In re Wands*, 858 F.2d at 737, 8 U.S.P.Q.2d at 1404; *In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 218-219 (C.C.P.A. 1976).

Finally, Applicants respectfully assert that the subject matter of claims 1 and 8-13 has been described in the specification in a manner adequate to enable one of skill in the art to make and use the claimed invention without undue experimentation. Applicants have described the complete chemical structure of SEQ ID NO: 1. For example, Applicants respectfully submit that, given the complete chemical structure of SEQ ID NO: 1, one of ordinary skill in the art would understand how to use the sequence of SEQ ID NO: 1 for the uses described in the specification, *e.g,,* identifying promoters and associated regulatory sequences (page 36, line 16 through page 38, line 6), and

identifying polymorphisms (page 39, line 6, through page 46, line 3). As stated above, patent applicants need not teach "conventional and well-known genetic engineering techniques." *E.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000). Patents "are written to enable those skilled in the art to practice the invention, not the public." *W.L. Gore & Assoc., Inc. v Garlock, Inc.*, 721 F.2d 1540, 1556, 220 U.S.P.Q. 303, 315 (Fed. Cir. 1983). Furthermore, the level of skill in this art is high, and the performance of routine and well-known steps cannot create undue experimentation even if it is laborious. *See In re Wands*, 858 F.2d at 737, 8 U.S.P.Q.2d at 1404; *In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 218-219 (C.C.P.A. 1976).

Accordingly, for at least these reasons, Applicants therefore respectfully request reconsideration and withdrawal of the enablement rejections under 35 USC § 112, first paragraph.

VI. Rejection under 35 U.S.C. § 112, First Paragraph (Written Description)

Claim 1 stands rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that allegedly lacks an adequate written description in the specification. Office Action at page 4. The Office alleges that "there is no written description as to what is a nucleic acid sequence of SEQ ID NO 1 which encodes the maize protein." Office Action at pages 4-5. Applicants respectfully disagree.

Applicants respectfully point the Examiner to the specification, which indeed provides written description support for claim 1. *See, e.g.,* specification at page 10, lines 1-7, at page 19, line 1 through page 20, line 12, and at page 25, line 21 through page 27, line 20.

Accordingly, for at least these reasons, Applicants respectfully request reconsideration and withdrawal of the written description rejection under 35 USC § 112, first paragraph.

VII. Rejection under 35 U.S.C. § 102(e)

Claim 9 stands rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Klann, U.S. Patent No. 6,068,974, filed on April 29, 1998. Office Action at page 5. The Office alleges that "[c]laim 9 is also rejected under 35 U.S.C. 102(e) as being anticipated by KLANN (6068974, issued 5/30/2000) with the same reasons as set forth in section 2 above." Office Action at page 5. Applicants respectfully disagree.

It is axiomatic that for prior art to anticipate under § 102, it has to meet every element of the claimed invention. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986). An anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device. *In re Donohue*, 766 F.2d 531, 226 U.S.P.Q 619 (Fed. Cir. 1985).

With regard to the phrase "or fragment thereof," Applicants respectfully point out that a grammatically consistent interpretation of the claim at issue would relate the phrase "or fragment thereof" in the preamble back to the phrase "maize protein" directly preceding it. Further, because the phrase "or fragment thereof" appears before the transition phrase "comprising", it is clear that it does not refer to a fragment of SEQ ID NO: 1. Moreover, Applicants assert that the Examiner has placed undue emphasis on the phrase "a nucleic acid sequence of" while simultaneously disregarding the recitation of SEQ ID NO: 1 in the claim. Applicants respectfully submit that the Examiner has erred in doing so. "Claims are not to be read in a vacuum, and limitations therein are to be interpreted in light of the specification in giving them their 'broadest reasonable interpretation.'" *In re Marosi*, 710 F.2d 799, 802, 218 U.S.P.Q. 289, 292 (Fed. Cir. 1983), quoting *In re Okuzawa*, 537 F.2d 545, 548, 190 U.S.P.Q. 464, 466 (C.C.P.A. 1976)(emphasis in original). See also M.P.E.P. § 2111.01 at 2100-48.

As such, the Examiner's interpretation of claim 9 to cover fragments of the claimed nucleic acid molecules as short as seven nucleotides is unreasonable and inconsistent with the teachings of the specification. Applicants therefore disagree that claim 9 reads on the teachings of Klann. However, in order to facilitate prosecution, and

without acquiescing to the Examiner's interpretation of claim 9, applicants have amended claim 9.

Pending claim 9 is directed to a nucleic acid molecule which encodes a maize protein or fragment thereof, *i.e.*, a fragment of a maize protein, comprising the nucleic acid sequence of SEQ ID NO: 1. Whatever U.S. Patent No. 6,068,974 teaches, it does not disclose SEQ ID NO: 1. Absent a teaching of each and every element of the claim, including the nucleotide sequence of SEQ ID NO: 1, the reference cited by the Examiner does not anticipate pending claim 9.

In view of the above, Applicants contend the rejection under 35 U.S.C. § 102(e) is improper. Reconsideration and withdrawal of this rejection is respectfully requested.

Conclusion

In view of the above, the presently pending claims are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass the application to issue. The Examiner is encouraged to contact the undersigned at (202) 942-5512 with respect to any unresolved issues remaining in this application.

Respectfully submitted,

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